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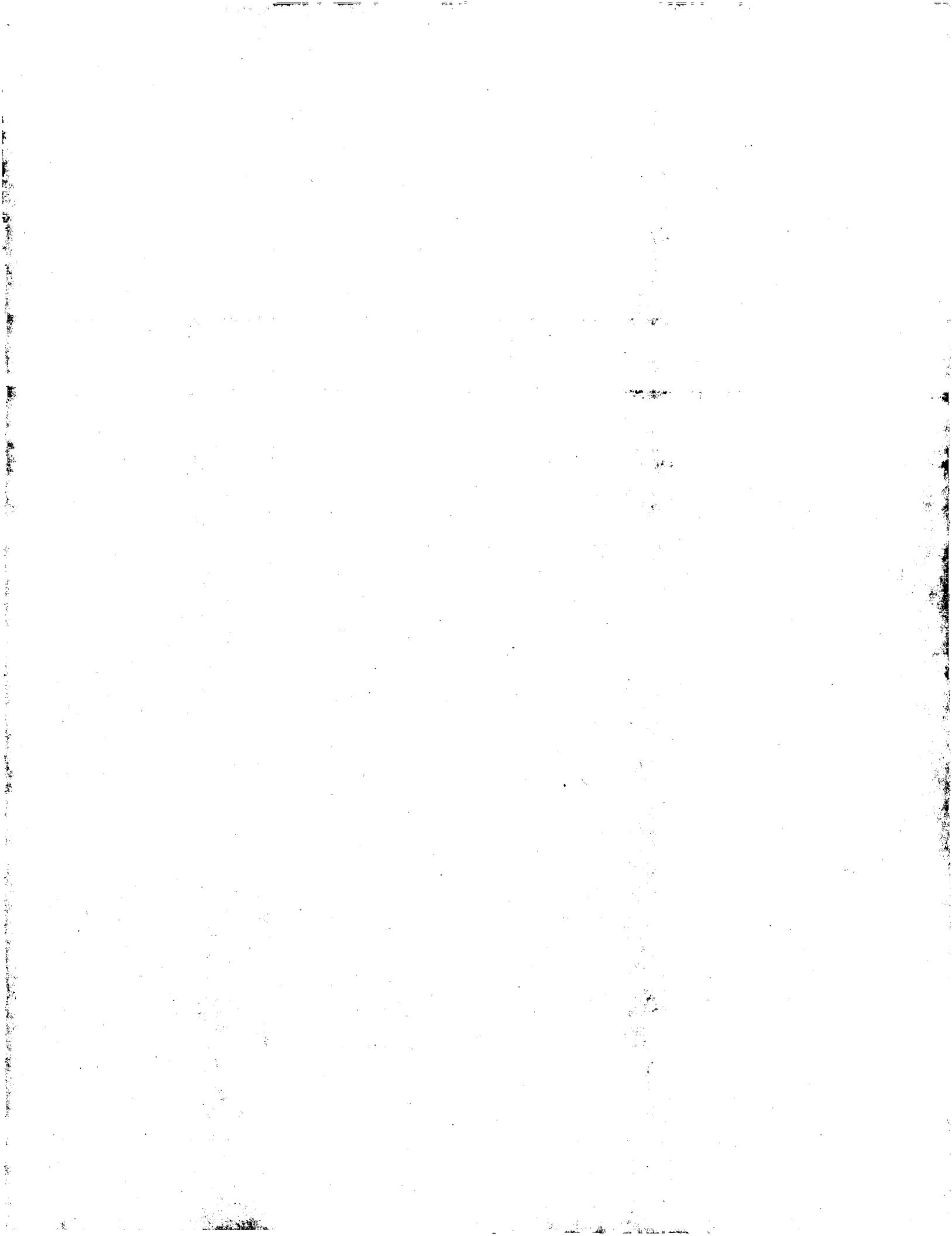
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| <p>(21) International Application Number: PCT/DK97/00253</p> <p>(22) International Filing Date: 9 June 1997 (09.06.97)</p> <p>(30) Priority Data:<br/>0750/96 5 July 1996 (05.07.96) DK</p> <p>(71) Applicant (for all designated States except US): NOVO NORDISK A/S [DK/DK]; Novo Allé, DK-2880 Bagsværd (DK).</p> <p>(72) Inventors; and</p> <p>(75) Inventors/Applicants (for US only): POULSEN, Jens, Ulrik [DK/DK]; Virumgade 54 C, DK-2830 Virum (DK). LJUNG-GREEN, Henrik [DK/DK]; Jonstrupvej 244 A, DK-2850 Ballerup (DK). CHRISTENSEN, Lars, Hofmann [DK/DK]; Smallegade 30B, 2.sal, DK-2000 Frederiksberg (DK).</p> <p>(74) Common Representative: NOVO NORDISK A/S; Corporate Patents, Novo Allé, DK-2880 Bagsværd (DK).</p>   |  | <p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ARPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b><br/>Without international search report and to be republished upon receipt of that report.</p> |   |
| <p>(54) Title: DOSE SETTING DEVICE</p>  |  |   |   |
| <p>(57) Abstract</p> <p>In a drug delivery device a dose to be apportioned from a cartridge is set by changing the relative position of co-operating dose setting elements (3, 5) and is injected by pressing a button (5) until this button abuts a stop (6). By operation of count up (7) or count down (8) buttons the dose is set and read into an electronic circuit (9) comprising a microprocessor and the dose setting movement of the dose setting elements relative to each other is performed by a motor (11) controlled by the circuit in accordance with the read in dose. The set dose is shown on a display (10). The motor (11) is further controlled to perform certain movements of the piston rod (3) so as retraction of this rod when a cartridge (1) is going to be changed an advancing of the piston rod to abutment with the piston (2) after the cartridge has been changed and further to advance this piston to expel air from the cartridge.</p> |  |   |   |

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### Dose Setting Device

The invention relates to drug delivery systems by which set doses may be apportioned from a cartridge and delivered, the dose setting being made by  
5 changing the relative position of cooperating dose setting elements and the delivery being made by pressing a button until it abuts a stop.

The deliverance may take place as an aerosol spray, an injection, or a high pressure jet which penetrates the skin so that the delivered material may be precipitated in the  
10 tissue beneath the skin.

The dose setting elements may be a threaded rod and a nut as in EP 327 910 wherein the threaded rod is a piston rod acting on a piston which presses out liquid from a cartridge in accordance with the distance the piston is moved. By dose setting  
15 a nut at the end of a hollow button surrounding a threaded piston rod is screwed along the piston rod away from a stop and thereby lifts the button up from the proximal end of the injection device. The injection is performed by pressing the button to move the nut back to the stop by which movement the piston rod and the piston is pressed into the cartridge a distance corresponding to the distance the nut was  
20 screwed away from the stop.

In another dose setting mechanism as described in WO 90/0038 a carrier, which may transport the piston rod in only a distal direction, is by the setting of a dose moved away from a stop and may thereafter by pressing an injection button be  
25 moved back to abutment with said stop.

In still another injection device as described in EP 0 245 312 a button with a push rod may be operated to reciprocate over a fixed distance. During part of its reciprocating movement the push rod drives a piston into a cartridge. Said part corresponds to a set dose which is set by varying a free space between the piston rod an  
30

the piston when the button and the push rod is in their not operated position.

- The size of set doses is mainly indicated by a pointer or through a window which is coupled to one of the dose setting elements and indicates a number corresponding
- 5 to the set dose on a scale coupled to the other dose setting element the size of the dose being proportional with the distance the two elements have been moved relative to each other. This fact sets a limit for the size of the figures on the scale although different initiatives has been taken to expand the space available for these figures. The dose setting is performed by turning a screw or a wheel or by rotating
- 10 two parts of the injection device relative to each other and currently monitor the size of the dose set. By some constructions of the dose setting mechanism it is not possible to reduce the set dose if the two dose setting elements have been moved to far in relation to each other, i.e. if a too large dose has been set. By other constructions it is necessary to make sure that the device is reset before a dose can
- 15 be set. A device which is very simple to use is aimed at. The simplest form of device should only show a very simple dose setting device and an injection button.

It is the object of the invention to provide a user-friendly injection device by which more of the known draw-backs are avoided.

- 20
- This is obtained by an injection device as described in the opening of this specification, which device is characterised in that the dose setting is read in into an electronic circuit and the dose setting movement of the dose setting elements relative to each other is performed by an electromechanical device, e.g. a motor,
- 25 controlled by the electronic circuit in accordance with the read in dose setting.

According to the invention the electronic circuit may appropriately comprise a micro-processor.

- 30 The use of an electric motor in an injection device is known but in such known

devices the motor is used to perform the injection. However, it has appeared that it is preferable to make the injection manually as this gives the user the possibility of adjusting the injection speed in accordance with the absorption of the injected liquid in the tissue. Further it is rather power consuming to perform the injection movement 5 and consequently the batteries which must have small physical dimensions will be exhausted very quickly.

- Combining electronic control and electromechanical setting of a dose enables the apparatus to intervene actively if anomalous or unintended conditions are detected 10 during a dose setting sequence or if a not allowed handling of the apparatus is detected, so as opening of the cartridge holder during the setting of a dose. The active intervention may comprise a resetting of the dose setting to a starting point corresponding to the dose =0 and then a reporting of a malfunction until the error has been corrected, e.g. by closing the cartridge holder. This way the risk for 15 erroneous doses and the doubts whether a correct dose is delivered or not may be overcome. When the error has been corrected or the unintended handling of the apparatus has stopped, the setting of the dose may be restarted from the starting position of the apparatus.
- 20 An electronically setting of the dose be performed by using one or two buttons by which a counting up or a counting down of a dose may be ordered to an electronic circuit.

The set dose may currently be shown on an electronic display and the counting may 25 be performed upwards as well as downwards. The use of an electronic display offer the advantage that the size of the figures in the display depends only on the size of the display. Also other presentation devices than a display may be used, e.g. a speech synthesizer circuit currently pronouncing the number corresponding to the set dose.

The setting may be obtained by reading the wanted dose into the electronic circuit which present the read in dose in the display an controls the motor to run in a direction to set the mechanic parts of the dose setting mechanism accordingly. When a signal from a position reader indicates that the mechanic parts has reached

5 a position corresponding to the set dose the electronic circuit will cause a stop of the motor.

The motor may be able to perform the mechanical setting at about the same speed as the counting up or down is performed on the display. If the mechanical setting is

10 not obtained or is unbearably delayed in relation to the showing of the display it is taken as an indication of exhausted batteries and an error is reported to the user, e.g. by switching of the display.

Alternatively the reading of the display may be a feed back from a position reader

15 reading the size of the mutual movement of the dose setting elements. In this way it is ensured that the dose setting is in accordance with the reading on the display as this reading is an expression of the actual relative position of the dose setting parts. In this embodiment an exhausted battery will result in a very slow or failing counting in the display.

20

In known motor driven delivery systems a set dose may be shown in a display and a count down may be shown concomitant with the motor driven injection. However, except from the showing of the display the set dose is not visually recognisable. In opposition thereto the electromechanical setting according to the invention will

25 ensure that the setting further is physically recognisable as the physical position of the dose setting parts relative to each other may be visually inspected.

A switch may be provided which is operated when the injection button is pressed home. The operation of the switch ensures that the injection button is in its zero

30 position before a new dose setting may be performed.

A further advantage by the device according to the invention is that limits may be set as an information read into the electronic circuit. If a maximum dose must not be exceeded the circuit may be so programmed that a number higher than the  
5 maximum number of units of the drug to be delivered cannot be read in into the electronic circuit.

Also the circuit may be programmed to set a predetermined dose every time the dose setting is operated. This may be of importance to people who are themselves  
10 unable to perform the setting.

The movement of the dose setting elements are recorded to the electronic circuit and is translated to a number indicating the set dose in units defined for the sort of medicine which is administered by the injection device. As medicine may occur with  
15 different concentrations and as from one type of medicine to another different volumes may corresponds to a unit, it is advantageous that the translation of movement into units is made electronically so that the same mechanical device may be made useable for different types and concentrations of medicine just by a programming of the circuit. The programming of the circuit may co-operate with a code on the  
20 cartridge so that the program is automatically adapted to the medicine in the cartridge and the correct amount is delivered when a dose is set by its number of units.

In the following the invention is described with references to the drawing which  
25 schematically shows an electronic dose setting device according to the invention.

A cartridge 1 is accommodated in a not shown housing. By the use of the device a piston 2 is pressed into the cartridge 1 to press out some of the content of this cartridge through a not shown needle which may be mounted at a distal end of the  
30 cartridge. The piston is moved by a piston rod 3 which is shown as a threaded rod

and forms a first dose setting element. A second dose setting element is a nut 4 with an internal thread co-operating with the external thread of the piston rod 3. A button with a bore accommodating an outer end of the piston rod 3 forms an integral part of the nut and forms an injection button 5. The injection button 5 may be pressed to move the piston 2 into the cartridge until the nut 4 abuts a stop 6 forming a part of the not shown housing. A pin 17 in the housing engages an axial track in the piston rod to block this piston rod against rotation relative to the housing.

When a dose is going to be set, the device is in an initial position with the nut 4 abutting the stop 6. The dose is set by activating one of a pair of dose setting buttons 7 and 8, one 7 for counting forward or up and another 8 for counting backward or down. The set dose is stored in an electronic circuit 9 and is displayed on a display 10. As long as the counting up button 7 is pressed the set dose is increased and the size of the dose may currently be followed on the display 10. If the counting up runs too far, the count down button 8 may be activated until the set dose is decreased to the size wanted.

The mechanical setting of the dose setting elements according to the electronically set dose is performed by an electric motor 11 having an output shaft provided with an elongated gear 12 which gear engages a toothing 13 at the periphery of the nut 4.

The motor 11 which may be controlled to run as well clockwise as anticlockwise is controlled from the electronic circuit to rotate the nut in accordance with the set dose. The rotation is measured by a position reader 16 which counts the number and direction of passing teeth.

To make sure that the electronically set dose is also mechanically set the display may be driven so that it does not show the setting until the feed-back signal from the position reader 16 confirms that the mechanical setting has taken place. Put in

another way, when the count up button 7 is activated the circuit 9 controls the motor 11 to rotate in a dose increasing direction and the display will then currently show how far the nut is rotated in a direction corresponding to increasing settings. When the count down button 8 is activated a decrease of the mechanically set dose is  
5 obtained and recorded in the same way.

Alternatively a number is counted up in the display by activating the count up button 7, and the motor is then controlled to set the dose setting parts in a relative position corresponding to the number in the display. The motor and the battery must be  
10 powerfull enough to ensure that the mechanical setting of the dose setting parts follows the counting up or down in the display very closely, i.e. with none or only a very small delay. When the delay exceeds a preset time, the electronic circuit may indicate an error, e.g. by switching off the display or by activating a "low battery" indicator.  
15

If the count down button 8 is activated when the display shows zero which reading corresponds to the position of the nut 4 when it abuts the stop 6, it shall not be possible to set a negative dose. This may be avoided either by the fact that the nut 4 operates a switch 15 mounted in the stop 6 by which operation a signal is sent to the  
20 circuit 9 to stop further operation of the motor 11 in the dose decreasing direction. Alternatively the circuit 9 may currently monitor the power consumption of the motor 11 and stop this motor when a rise in power consumption indicates that the nut 4 is abutting the stop 6.

25 Correspondingly setting of a dose which exceed the amount of remaining medicine in the cartridge may be avoided by providing a stop 14 at the outer end of the piston rod the position of this stop being so that the cartridge is just empty when the nut 4 is screwed up to this stop and pressed to abutment with the stop 6. When the motor during setting of a dose is operated in the dose increasing direction to move the nut  
30 4 towards the outer end of the piston rod suddenly increases its power consumption

due to the fact that the nut 4 has reached the stop 14 on the piston rod 3 it is by the circuit taken as an indication of the fact that the set dose cannot be further increased and the motor will be stopped and the size of the set dose corresponding to the medicine remaining in the cartridge may be read out on the display 10.

5

By the motor driving of the mechanical setting the realisation of the stops becomes very simple as the power of the motor is limited and the stops only have to influence the power consumption of the motor recognisably whereas manually operated devices may be exposed to heavy forces which the elements in the device shall be

- 10 able to stand without breaking at the same time as the elements shall be miniaturised if the device shall not be inconveniently bulky. In fact the stops may be made pure electronically. It may be stored in the electronic circuit how many units of a drug the cartridge contains and the number of units delivered may be cumulated so that the circuit can calculate the number of units left in the cartridge and set this
- 15 number as an upper limit for the dose which can be set.

The switch 15 in the stop may serve the function of indicating when the injection button is pressed home and an injection is completed. When the injection is pressed home it may further be locked in this position until a new dose is going to be set.

- 20 When a signal indicating that an injection is completed is sent to the circuit 9 the size of the just completed injection is stored and may on demand be showed in the display until the next dose is set. This demand may be signalled in different ways, e.g. by a short pressing of one of the dose setting buttons, by a switch activated when a protection cap is removed from the housing, or by operating a button
- 25 releasing the injection button from its pressed home position.

With the injection button in its pressed home position the motor can be used to automatically perform other functions to make the use of the device less complicated. When a cartridge has to be changed a cartridge holder shall be

- 30 opened, the piston rod shall be moved back to a retracted position to clear a space

for a new cartridge, the new cartridge shall be inserted, the cartridge holder shall be closed, and the piston rod shall be moved towards the piston to back-up this piston and then be moved further forwards to move the piston into the cartridge until air in this cartridge is pressed out through an injection needle. A switch detecting the  
5 opening of the cartridge holder sends a signal to the circuit to obtain operation of the motor in an dose decreasing direction. By this operation the nut may abut the stop 6 in a sliding way and draw the piston rod backward. When an increase in the motor power consumption indicates that the piston rod may not be drawn further backwards, the motor is stopped and the empty cartridge may be removed and  
10 replaced by a new full one. When the cartridge holder is closed the motor may be controlled to rotate in the opposite direction and if the nut is in some way blocked against movement along the piston rod, the piston rod will instead be moved into the cartridge and abut the piston. This abutment is indicated by a rise in the power consumption. The piston rod may move the piston further into the cartridge to drive  
15 out air from the cartridge on the condition that a needle is mounted and the device is held with the needle pointing up. When the air is pressed out of the cartridge a new rise in the power consumption indicates that the air is pressed out and now liquid is pressed out. This power consumption pattern may be stored in the circuit so the motor may be stopped when it is detected that liquid is beginning to be pressed out.  
20 Hereafter the device is ready for use. This ability to discriminate between the out pressing of air and liquid may be used for an automatic air shot function which may be activated before each use of the injection device.

**Claims**

1. A drug delivery device by which set doses are apportioned from a cartridge and delivered, the dose setting being made by changing the relative position of co-  
5 operating dose setting elements and the delivery being made by pressing a button until it abuts a stop **characterised** in that the dose setting is read into an electronic circuit and the dose setting movement of the dose setting elements relative to each other is performed by an electromechanical device, e.g. a motor, controlled by the circuit in accordance with the read in dose setting.

10

2. A device according to claim 1, characterised in that the electronic circuit comprises a microprocessor.

15 3. A device according to claim 1 or 2, **characterised** in that dose setting switches are provided by the operation of which the dose setting may be stepwise increased or decreased.

4. A device according to claim 1, 2 or 3 **characterised** in that limitations on set doses are made electronically.

20

5. A device according to claim 1, 2, 3 or 4 **characterised** in that the set dose is communicated electrically to the user to be shown on an electronic display or to be read by a speech synthesizer.

25 6. A device according to claim 5, **characterised** in that the dose represented by the relative position of the dose setting elements is continuously compared with the dose communicated to the user and the motor is controlled to move these elements to balance a possible difference

30 7. A device according to claim 5, **characterised** in that the dose setting activates

the motor and the showing of the display records the relative position of the dose setting elements provided by the motor.

8. A device according to anyone of the preceding claims, **characterised** in that the  
5 button is coupled to the dose setting elements so that it is lifted from the device a distance corresponding to the set dose

9. A device according to anyone of the preceding claims, **characterised** in that a switch is provided which is operated when the button is pressed home.

10

10. A device according to anyone of the preceding claims, **characterised** in that a switch is provided which detects closing or opening of a cartridge holder.

15

11. A device according to claim 10 characterised in that the electronic circuit is so programmed that a detection of an opening of the cartridge holder when the injection button is in a pressed home position activates the motor to run in a piston retracting direction, until the piston rod is fully retracted.

20

12. A device according to claim 11, characterised in that the electronic circuit is so programmed that detection of a closing of the cartridge holder when the injection button is in a pressed home position activates the motor to run in a piston rod advancing direction until an increase in its power consumption indicates that the piston rod abuts a piston in a cartridge.

25

13. A device according to claim 11 and 12, characterised in that the a air shot button is provided which when the injection button is in its pressed home position activates the motor to run in its rod advancing direction until its power consumption when compared with a value stored in the electronic circuit indicates that liquid and not air is pressed out through an injection needle.

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14. Device according to anyone of the preceding claims, characterised in that the electronic circuit monitors the signals it receives and alert the user if a not allowed signal is received.

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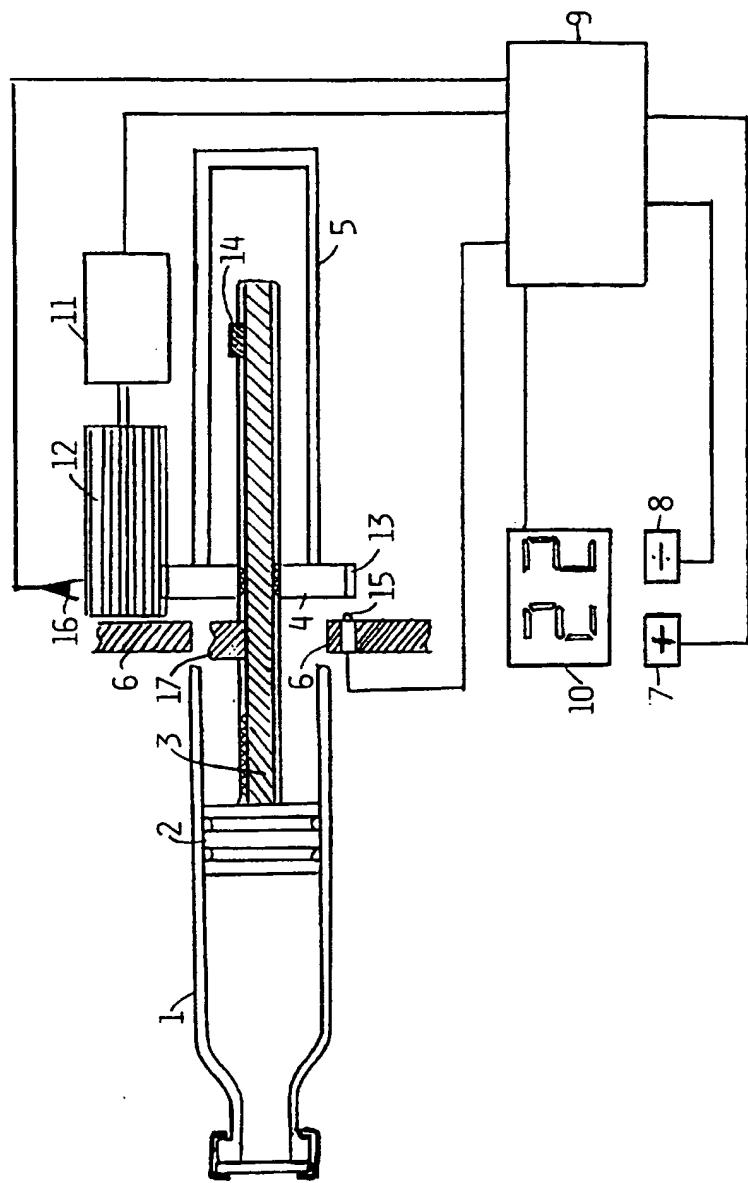


Fig. 1

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| CM | Cameroon                 | KR | Republic of Korea                     | PL | Poland                                    |    |                          |
| CN | China                    | KZ | Republic of Korea                     | PT | Portugal                                  |    |                          |
| CU | Cuba                     | KZ | Kazakhstan                            | RO | Romania                                   |    |                          |
| CZ | Czech Republic           | LC | Saint Lucia                           | RU | Russian Federation                        |    |                          |
| DE | Germany                  | LJ | Liechtenstein                         | SD | Sudan                                     |    |                          |
| DK | Denmark                  | LK | Sri Lanka                             | SE | Sweden                                    |    |                          |
| EE | Estonia                  | LR | Liberia                               | SG | Singapore                                 |    |                          |

1  
INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 97/00253

**A. CLASSIFICATION OF SUBJECT MATTER****IPC6: A61M 5/172, A61M 5/24 // A 61 M 5/20**

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

**IPC6: A61M**

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

**SE,DK,FI,NO classes as above**

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**WPI, CLAIMS****C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                       | Relevant to claim No. |
|-----------|--|-----------------------|
| A         | DE 3307810 A1 (DELTA MEDICAL INDUSTRIES),<br>15 Sept 1983 (15.09.83), figure 1,<br>abstract<br><br>----- | 1-14                  |

 Further documents are listed in the continuation of Box C. See patent family annex.

|   |  |
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| "A" document defining the general state of the art which is not considered to be of particular relevance  | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  |
| "E" earlier document but published on or after the international filing date  | "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone   |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "O" document referring to an oral disclosure, use, exhibition or other means  | "&" document member of the same patent family  |
| "P" document published prior to the international filing date but later than the priority date claimed  |  |

Date of the actual completion of the international search

Date of mailing of the international search report

30 December 1997

02 -01- 1998

Name and mailing address of the ISA/  
Swedish Patent Office  
Box 5055, S-102 42 STOCKHOLM  
Facsimile No. + 46 8 666 02 86

Authorized officer

May Hallne  
Telephone No. + 46 8 782 25 00

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

02/12/97

International application No.  
PCT/DK 97/00253

| Patent document cited in search report | Publication date | Patent family member(s)       | Publication date     |
|--|------------------|-------------------------------|----------------------|
| DE 3307810 A1                          | 15/09/83         | JP 58221955 A<br>US 4435173 A | 23/12/83<br>06/03/84 |